

observed. Longer follow-up of a larger number of patients will be ready for presentation in October.

## TCT-61

### Optimized External Focused Ultrasound for Renal Sympathetic Denervation – Wave II trial

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**Background:** We previously reported the results of the WAVE 1 trial for Renal Sympathetic Denervation in twenty-four patients with refractory hypertension using the Kona Surround Sound System. Six month results demonstrated a 27mmHg reduction in systolic blood pressure in the study. This technology utilizes external focused ultrasound navigated by a targeting catheter in the renal artery. The WAVE 1 protocol involved making 18 focused lesions over 12.6 minutes on each side. This study (WAVE II) is evaluating the safety and efficacy of an optimized treatment protocol in which 14 focused lesions produced over 2.8 min on each side were utilized to create sympathetic denervation.

**Methods:** Thirteen patients (8 men and 5 women; median age: 60 years), with resistant arterial hypertension underwent bilateral externally focused ultrasound utilizing a 5F intravascular catheter for targeting and tracking. Patients were on a minimum of three antihypertensive medications. All treatments were performed in patients under deep analgesic-sedation. The procedure was performed using the 2.8 min protocol for each side and targeting was directed to just proximal to the bifurcation of the renal artery.

**Results:** During and after the procedure no serious complications were observed. Unlike the WAVE I trial, only one of 13 patients complained of back pain following the index procedure and this resolved within 4 days. To date, Eight patients reached the 6-week follow up time point and Systolic BP decreased by 18 mmHg and diastolic BP was unchanged.

**Conclusions:** The optimized externally focused ultrasound protocol was efficient and well tolerated. There were not serious adverse events reported and 6 weeks results for eight patients were tracking similarly as patients treated in the WAVE I study which ultimately resulting in a 27 mmHg reduction in systolic BP. Since externally focused ultrasound can be performed safely, quickly, and effectively, the development of a fully non-invasive system should offer even greater benefits for patient care.

## TCT-62

### Preliminary Result of the Rapid Renal Sympathetic Denervation for Resistant Hypertension Using the Maya Medical OneShot™ Ablation System (RAPID) Study

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**Background:** Resistant hypertension remains a major health concern despite the availability of effective pharmacological agents. Catheter-based renal sympathetic denervation has emerged as a therapeutic option for patients with resistant hypertension. Recent clinical reports show that ablation of the renal sympathetic nerves using radiofrequency (RF) energy is safe and effective. The OneShot™ Renal Denervation System (Covidien, Campbell, CA) is a balloon-based RF system using a mounted spiral electrode with a unique feature of irrigation of the vessel wall during treatment. The non-compliant balloon is inflated under low pressure (1 atm) in the renal artery, and the electrode delivers RF energy with a single 2-minute treatment.

**Methods:** RAPID is a prospective, multicenter, single-arm study that enrolled 50 patients at 11 clinical sites in Europe and New Zealand. Patients were considered for enrollment based on having an office systolic blood pressure (SBP)  $\geq 160$  mmHg despite treatment with a regimen three or more antihypertensive medications including a diuretic. The follow-up period is at 1, 3, 6, 12, 24 and 36 months. The primary safety endpoints include acute procedural safety, defined as the overall rate of serious adverse events (SAEs) and adverse device effects (ADEs) at discharge; and chronic procedural safety, defined as the overall rate of SAEs and ADEs at 6 months. The primary effectiveness endpoint is the rate of office systolic blood pressure reduction  $> 10$  mmHg at 6 months compared to baseline.

**Results:** Fifty patients were enrolled with a mean age of 63.0 years (58.0% male). Patients were on a mean of 4.9 antihypertensive drugs at baseline. The mean baseline office systolic and diastolic blood pressure measurements were  $181.6 \pm 20.8$  and  $95.5 \pm 15.5$  mmHg, respectively. Results at 1 month showed a significant reduction,  $-17.7 \pm 7$  mmHg ( $p < 0.0001$  and  $p = 0.0008$ ), in both systolic and diastolic blood pressure measurements. An update of the ongoing study endpoint results will be presented at TCT.

**Conclusions:** Preliminary results of the RAPID study demonstrate safe delivery of RF energy for renal sympathetic denervation.

## TCT-63

### Drug-Coated Balloon (DCB) for Peripheral Arteries: Postdilatation of Nitinolstents with DCB or plain balloon in the superficial femoral artery – Interim results of the Freeway Stent Study

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**Background:** The restenosis rate of stents is still a major limitation of arterial interventions. The Freeway Stent Study investigates the inhibition of restenosis by Paclitaxel-eluting balloon dilatation post stent PTA versus stenting PTA with plain balloon postdilatation in the treatment of the superficial femoral artery. By this, the Freeway Stent Study follows a new approach to potentially overcome the problem of restenosis.

**Methods:** The Freeway Stent Study is a randomized, controlled multicenter trial which is conducted in 15 centers in Germany and Austria. This study intends to enroll 200 patients being randomized in a 1:1 relation to either nitinol stenting followed by drug-coated balloon Freeway™ (Eurocor GmbH) postdilatation or stenting with plain balloon post dilatation. Primary endpoint is clinically driven target lesion revascularization at 6 months. Further, secondary safety and efficacy endpoints such as late lumen loss at 6 months, patency rate and major adverse events are investigated.

**Results:** 150 patients have already been enrolled. More than 100 have completed the 6 months follow up. The results show a favorable outcome for the DCB arm in relation to the TLR rate in this patient population which presented predominately with occlusions. The results are supported by the clinical outcome of patency rate, ABI index and presentation according to Rutherford.

**Conclusions:** In this trial the Freeway Paclitaxel-coated balloon is investigated in a new approach to decrease the restenosis rate of stents in patients with stenting in the SFA. Interim results will be provided to show that DCB might provide an advantage also in these patients to overcome the existing limitations of peripheral artery disease treatment.

## TCT-64

### Are Stent Grafts The Solution For In-Stent Restenosis After SFA Stenting

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**Background:** Tackling in-stent restenosis (ISR) in the superficial femoral artery (SFA) has some challenges. To date literature review reveals only very limited data on ISR in peripheral arteries. Current available treatments do not yield satisfactory results, demonstrating the need of a treatment with a better outcome. The Viabahn endoprosthesis with a heparin bioactive surface offers high flexibility when deployed in the SFA and the coating provides an enhanced hemocompatibility.

**Methods:** The RELINE trial is a prospective, randomized, multi-center, international, controlled trial in which enrollment was allowed to continue until 80 patients meet the eligibility criteria. Between June 2010 and February 2012, 100 patients were enrolled. The first primary endpoints is primary patency at 12 months, defined as no evidence of restenosis or occlusion within the originally treated lesion based on color-flow duplex ultrasound (CFDU) measuring a peak systolic velocity ratio  $\leq 2.5$  and without target lesion revascularization (TLR) within 12 months. The second primary endpoint is the proportion of subjects who experience serious device-related adverse events within 30 days post-procedure.

**Results:** The preliminary analysis is based on the intention-to-treat total of 100 patients. 47 (47.0%) patients were randomized to the VIABAHN ISR group and 53 (53.0%) patients were randomized to the POBA group. The demographic data was comparable in both treatment groups. In the VIABAHN ISR group there were 34 (72.3%) men and the mean age was 67.34 (49-86) years. In the POBA group, 35 (66.0%) patients were male and the mean age was 69.26 (48-87) years. The survival analysis shows a primary patency rate at 6 months of 94.4% for the VIABAHN ISR group and 60.7% for the POBA group ( $p < 0.001$ ). Freedom of TLR at 6 months is 94.3% in the VIABAHN ISR group and 60.4% in the POBA group ( $p < 0.001$ ). These data are preliminary, indicated by the 24 patients at risk in the VIABAHN ISR group and 14 patients at risk in the POBA group at 6 months.

**Conclusions:** With very good, but preliminary results, the full 12 months data analyses are expected to be able to show a similar trend in patency outcome, which will

## TCT-65

### Directional Atherectomy is an Effective Treatment Option for Infrapopliteal Lesions in Patients with Critical Limb Ischemia

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**Background:** The endovascular treatment of infrapopliteal arterial disease in patients with critical limb ischemia (CLI) is complex and seldom studied. Directional atherectomy (DA) revascularizes by removing the atherosclerotic plaque and minimizing the need for balloon angioplasty and/or stenting. The DEFINITIVE LE study was